REMARKS

Claims 26 is amended.
Claims 27-30 are cancelled.
Claim 31 is new.

Claim Rejection 35 U.S.C. §103

The claims as amended are no longer obvious over Yuksel (Ophthalmologica, 1999, 213(4), 228-233). To establish a prima facie case of obviousness "the prior art reference (or references when combined) must teach or suggest all the claim limitations" MPEP 2143. The present claim 26 states that "said composition is administered twice a day or less often." The "composition" referred to in the claim is a "composition comprising brimonidine at a concentration of about 0.2% by weight and timolol at a concentration of about 0.5% by weight." The Yuksel reference does not teach this limitation. Yuksel describes a single administration of 0.2% brimonidine tartrate followed by a single administration of 0.5% timolol five minutes later. The brimonidine was added once, and the intraocular pressure was measured every hour. The patients receiving this treatment were already on timolol therapy. For the patients in the adjunctive combination group, the IOP reached a minimum of about 17 mm Hg at 4 hours which increased by about 2 mm Hg to about 19 mm Hg at 8 hours (Figure 1). Thus, the effect of the brimonidine is fairly short-lived, and frequent administration of the brimonidine would be expected. In fact, the FDA recommends three times a day administration of brimonidine for glaucoma (see enclosure). By contrast, the FDA recommends twice a day administration of timolol. The reference does not teach or suggest what a continuing combination dosage regime may be. Thus, the limitation that "said composition is administered twice a day or less often" is not taught or suggested in the prior art, and a prima facie case of obviousness does not exist.

Alternatively, claim 31 adds the limitation that "brimonidine is administered only in the composition." Without admitting any prima facie obviousness of claim 26, even if a person of ordinary skill in the art did administer the composition twice a day, she would add a supplemental dose of brimonidine in the middle of the day to provide the FDA

recommended dosages for both brimonidine (tid) and timolol (bid, see enclosure). Thus, the reference does not suggest to the person of ordinary skill in the art that "brimonidine is administered only in the composition." Therefore, even if a prima facie case of obviousness could be made for claim 26, no prima facie case would exist for claim 31.

In light of the points made above and the amendments made to the claims, the Applicants assert that all of the claims meet the statutory requirements for patentability, and therefore respectfully request that the Examiner remove the rejections and pass the application to issue.

Please charge Deposit Account 01-0885 for fees related to this response.

Respectfully submitted,

Date: 5/2/06

Brent A. Johnson
Registration No. 51,851
Agent of Record
Telephone: 714/246-4348
Telecopier: 714/246-4249

Please address all correspondence and inquiries to:

Brent A. Johnson (T2-7H)
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612
Tel: 714.246.4348
Fax: 714.246.4249

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